

REMARKS

In the Office Action mailed September 1, 2009, the Examiner issued a Requirement Under 35 U.S.C. §§ 121 and 372 requiring Applicants to elect one of the following groups:

- I. Claims 1-36, 79 and 80, drawn to a method for screening molecular markers.
- II. Claims 37-75, 77, 78 and 81, drawn to identifying classifiers for a trait.
- III. Claim 76, drawn to a system for analyzing the blood of a test subject.

In response, Applicants' elect Group III, directed to a system for analyzing the blood of a test subject.

Claims 1-81 were pending in this application. Applicants have canceled claims 1-75 and 77-81 without prejudice to Applicants' right to pursue the subject matter of the canceled claims in this application or a related application(s). Applicants have amended claim 76 and have added new claims 82-98. Amended claim 76 and new independent claims 87 and 93 claim a method of profiling gene expression in a human test subject drawn to analyzing the blood of a test subject by applying a classifier to data, in accordance with claim 76 as examined. Accordingly, Applicants submit that amended claim 76 and new claims 82-98 are directed to similar subject matter as elected Group III. Support for claiming a method of profiling gene expression in a human test subject can be found in the specification and claims as filed, at least at paragraph [0421] of the published application (US 2007/0269804 A1).

Claim the limitations of applying a classifier to a sample dataset representing levels of expression in a blood sample of the test subject of each marker of a marker set consisting of HSPCA, IKBKAP, IL13RA1, LAMC1, MAFB and PF4, to thereby classify the test subject into a class representing human subjects having mild osteoarthritis or a class representing human subjects not having osteoarthritis, where the classifier is able to discriminate between human subjects having mild osteoarthritis and human subjects not having osteoarthritis, and where the classifier is derived from data representing a level of expression of each marker of the marker set in blood samples of human subjects having mild osteoarthritis and in blood samples of human subjects not having osteoarthritis. Support for claiming these elements can be found in the published application, at least at section 6.1 entitled "Evaluating Osteoarthritis Classifiers Using ROC Curves" starting at paragraph [0579].

New claims 83 and 86 depending directly or indirectly from amended independent claim 76, new claims 89 and 92 depending directly or indirectly from new independent claim 87, and new claims 95 and 98 depending directly or indirectly from new independent claim 93 limit the classifier to one which is "identified as classifier 100000252". New claims 82

and 85 depending directly or indirectly from amended claim 76, new claims 88 and 91 depending directly or indirectly from new claim 87, and new claims 94 and 97 depending directly or indirectly from new claim 93 limit the classifier to one which is “based on a multiple regression equation”. Support for limiting the classifier to one which is identified as “classifier 100000252” or which is “based on a multiple regression equation” can be found in the published application at least at section 6.1, Figure 8 and paragraph [0249]. Namely, section 6.1 sets forth classifier 100000252, and teaches that this classifier is derived from expression levels of HSPCA, IKBKAP, IL13RA1, LAMC1, MAFB and PF4 in blood samples of subjects having mild osteoarthritis and in blood samples of subjects not having osteoarthritis, and teaches that it has a significant ability to discriminate between subjects having mild osteoarthritis and subjects not having osteoarthritis (Figure 8 depicts the ROC curve of classifier 100000252 as labeled with the abbreviation “252”). Additionally, paragraph [0249] of the published application teaches the relevant use of multiple regression equations, and teaches that an equation having the format of classifier 100000252 corresponds to a multiple regression equation.

Amended independent claim 76, new claim 90 depending from new independent claim 87, and new claim 96 depending from new independent claim 93 each claim the limitation of obtaining the sample dataset by “measuring the level of expression of each marker of the marker set in the blood sample of the test subject”. Support for this limitation can be found in the published application, at least at section 6.1.

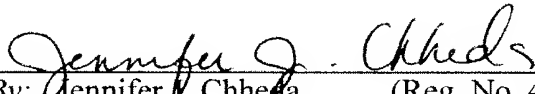
Claim 84 depending from independent claim 76, and new independent claims 87 and 93 each claim the limitation of applying the classifier to the sample dataset “using a computer programmed to apply the classifier to a dataset representing the level of expression of each marker of the marker set in a blood sample of a human individual to thereby classify the human individual into the class representing human subjects having mild osteoarthritis or the class representing human subjects not having osteoarthritis”. Support for this limitation can be found throughout the published application, including at paragraph [0575] which teaches use of programmed computers for implementing methods and systems of the disclosure, paragraph [0577] which specifically teaches the use of suitably configured computers for applying classifiers of the disclosure towards a wide variety of medical applications relating to diagnostics, and paragraph [0578], which introduces section 6.1, and which teaches computers and computer programs for providing health care exemplified firstly by section 6.1 at which the claims find significant support, as described above.

Accordingly, the claim amendments do not constitute new matter. Upon entry of this Amendment, claims 76 and 82-98 will be pending the application.

Applicants respectfully request that the above-made amendments and remarks be considered and entered into the application. The Examiner is invited to telephone the undersigned to discuss any questions concerning the application. An early allowance is earnestly sought.

Respectfully submitted,

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